PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
03PCP0012		
International application No.	International filing date (*day/month/year*)	Priority Date (*day/month/year*)
PCT/KR 2003/001310	2 July 2003 (02.07.2003)	3 July 2002 (03.07.2002)

International Patent Classification (IPC) or national classification and IPC

IPC[7]: C12N 15/62, C12N 15/82

Applicant

NEXGEN BIOTECHNOLOGIES, INC.

1. This international preliminary examination report has been prepared by this International Preliminary Examination Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 3 sheets, including this cover sheet.

   ☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of _____ sheets.

3. This report contains indications relating to the following items:

   I. ☒ Basis of the opinion

   II. ☐ Priority

   III. ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

   IV. ☐ Lack of unity of invention

   V. ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

   VI. ☐ Certain documents cited

   VII. ☐ Certain defects in the international application

   VIII. ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
03.02.2004	27 August 2004 (27.08.2004)
Name and mailing address of the IPEA/AT Austrian Patent Office Dresdner Straße 87 A-1200 Vienna Facsimile No. 1/53424/200	Authorized officer MOSSER R. Telephone No. 1/53424/437

Form PCT/IPEA/409 (cover sheet) (July 1998)

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/KR 2003/001310

I. Basis of the report

1. With regard to the elements of the international application:*

☒ the international application as originally filed

☐ the description:
pages _____, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____.

☐ the claims:
pages _____, as originally filed
pages _____, as amended (together with any statement) under Article 19
pages _____, filed with the demand
pages _____, filed with the letter of _____.

☐ the drawings:
pages _____, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____.

☐ the sequence listing part of the description:
pages _____, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____.

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.
These elements were available or furnished to this Authority in the following language _____ which is:

☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).

☐ the language of publication of the international application (under Rule 48.3(b)).

☐ the language of the translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

☐ contained in the international application in printed form.

☐ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority in written form.

☐ furnished subsequently to this Authority in computer readable form.

☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☐ The amendments have resulted in the cancellation of:

☐ the description, pages _____.

☐ the claims, Nos. _____.

☐ the drawings, sheets/fig _____.

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

** Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as „originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).*

*** Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.*

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/KR 2003/001310

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims 1-8	YES
	Claims ___	NO
Inventive step (IS)	Claims 1-8	YES
	Claims ___	NO
Industrial applicability (IA)	Claims 1-8	YES
	Claims ___	NO

Citations and explanations (Rule 70.7)

The following documents have been cited in the Search Report:

D1: US 5716802 A
D2: WO 98/21348 A1
D3: WO 01/16339 A1

D1 concerns the expression of human serum albumin in plants. D2 is directed to the expression of EGF in plants and D3 deals with the expression of fusion proteins in plant cells. None of the documents concerns the expression of a fusion polypeptide comprising EGF and human serum albumin (HSA) which is the subject-matter of the present application. The expression of human proteins in plants is possible. However it is very difficult to establish stable expression systems. A person skilled in the art could not expect that the stabilisation of human EGF with HSA leads to good results. The application shows examples which disclose interesting details about the plants, vectors and expression conditions so that a successful protein manufacture can be carried out. That means the inventive step of the subject-matters of the claims 1-8 is supported by the description. Accordingly novelty and inventive step are recognized for the subject-matters of claims 1-8. Industrial applicability is given for the subject-matters of claims 1-8.